Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Contract/Lab: All Laboratories

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 96

Report Date: 03/20/2010

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	058812305	03/21/01	727	50(3)	26(673)	509.7	Formamide
Battelle Columbus Laboratory	052000505	01/21/04	727	50(3)	30(679)	498.5	Ginseng
Battelle Columbus Laboratory	059501107	03/06/02	727	50(3)	22(673)	510.3	5-(Hydroxymethyl)-2-furfural
					Female		
Battelle Columbus Laboratory	058812305	03/20/01	730	50(5)	38(703)	358.3	Formamide
Battelle Columbus Laboratory	052000505	01/22/04	728	50(5)	36(700)	355.0	Ginseng
Battelle Columbus Laboratory	059501107	03/07/02	728	50(5)	31(679)	332.2	5-(Hydroxymethyl)-2-furfural

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 97

Report Date: 03/20/2010

Route: GAVAGE Vehicle: WATER

			Male				Female	
#All Organs: Benign Tumors		45/50 (90%)	49/50 (98%)	50/50 (100%)		43/50 (86%)	42/50 (84%)	46/50 (92%)
Overall Incidence	Total	144/150 (96%)	Mean 96%	SD 5.29%	Total	131/150 (87.33%)	Mean 87.33%	SD 4.16%
#All Organs: Malignant Tumors		05/50 (50%)	00/50 /500/	25/50 (70%)		45/50 (200()	40/50 (00%)	40/50 (200/)
Overall Incidence	Total	25/50 (50%) 86/150 (57.33%)	26/50 (52%) Mean 57.33%	35/50 (70%) SD 11.02%	Total	15/50 (30%) 41/150 (27.33%)	10/50 (20%) Mean 27.33%	16/50 (32%) SD 6.43%
#All Organs: Malignant and Benign To								
Overall Incidence	Total	48/50 (96%) 147/150 (98%)	49/50 (98%) Mean 98%	50/50 (100%) SD 2%	Total	49/50 (98%) 142/150 (94.67%)	45/50 (90%) Mean 94.67%	48/50 (96%) SD 4.16%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Hemangiosarcoma or He								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Page: 98

Report Date: 03/20/2010

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: **Histiocytic Sarcoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Leukemia: Erythrocytic 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 15/50 (30%)18/50 (36%)28/50 (56%)10/50 (20%)6/50 (12%) 9/50 (18%) Overall Incidence 61/150 (40.67%) Mean 40.67% SD 13.61% 25/150 (16.67%) Mean 16.67% SD 4.16% Total Total #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Benign, Malignant, NOS 2/50 (4%)2/50 (4%)2/50 (4%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% 2/150 (1.33%) Mean 1.33% SD 2.31% Total 6/150 (4%) Mean 4% Total

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 03/20/2010

**Page**: 99

Species: RATS Strain: F 344/N Route: GAVAGE Vehicle: WATER

			Male				Female	
#All Organs: Mesothelioma: Malignant		2/50 /40/	2/50 (40()	2/50 (40/)		2/50 (40()	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	2/50 (4%) 6/150 (4%)	2/50 (4%) Mean 4%	2/50 (4%) SD 0%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
#All Organs: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#All Organs: Osteosarcoma or Osteoma								4/50 (004)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Adrenal Cortex: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Adrenal Cortex: Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 100
Report Date: 03

			Male		Female				
Adrenal Medulla: Ganglioneuroma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Adrenal Medulla: Hemangioma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Adrenal Medulla: Pheochromocytoma Beni	gn	9/50 (18%)	4/50 (8%)	5/50 (10%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	18/150 (12%)	Mean 12%	SD 5.29%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Adrenal Medulla: Pheochromocytoma Com						0/50 (0%)	0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Adrenal Medulla: Pheochromocytoma Malig									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Adrenal Medulla: Pheochromocytoma: Ben	ign, Complex								
Overall Incidence	Total	9/50 (18%) 18/150 (12%)	4/50 (8%) Mean 12%	5/50 (10%) SD 5.29%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 101

			Male				Female			
#Bone: Chondrosarcoma					,					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 ( SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Bone: Chondrosarcoma or Chond	roma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 ( SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Bone: Chordoma										
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 ( SD 1.15%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Bone: Osteoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 ( SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
fBone: Osteosarcoma										
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 ( SD 1.15%	(0%)	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
#Bone: Osteosarcoma or Osteoma										
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 ( SD 1.15%	(0%)	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 102

			Male				Female	
*Brain: Astrocytoma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	2/52 (224)	0/50 (004)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Malignant		(00)	(201)				2/52 (221)	(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Glioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig	n							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Brain: Medulloblastoma Mal			•••••				•••••	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 103

Report Date: 03/20/2010

Route: GAVAGE Vehicle: WATER

			Male			Female			
Brain: Oligodendroglioma Beniç	gn								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: Oligodendroglioma Malig									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: Oligodendroglioma, Glio	ma, or Astrocy	toma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Brain: Osteosarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: Schwannoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Clitoral/Preputial Gland: Adenoma									
Overall Incidence	Total	1/50 (2%) 6/150 (4%)	0/50 (0%) Mean 4%	5/50 (10%) SD 5.29%	Total	2/50 (4%) 6/150 (4%)	1/50 (2%) Mean 4%	3/50 (6%) SD 2%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 104

			Male				Female	
Clitoral/Preputial Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		2/50 (4%)	0/50 (0%)	6/50 (12%)		2/50 (4%)	2/50 (4%)	3/50 (6%)
verall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 6.11%	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Ear: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Esophagus: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 105

			Male				Female	
#Esophagus: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Eye: Schwannoma Malignant		0/50 (00)	0/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Harderian Gland: Carcinoma					•••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Heart: Schwannoma Benign					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 106

			Male					Female	
*Heart: Schwannoma Malignant					,				
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Colon/Rectu Adenoma	m:								
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Colon/Rectu Carcinoma	m:								
		0/50 (0%)	0/50 (0%)		(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)		(0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Colon/Rectu Hemangioma	m:								
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 107

			Male			Female			
#Intestine Small: Duodenum Leiomyoma	:								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
#Intestine Small: Ileum: Adenoma		•••••	•••••			•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
fIntestine Small: Jejunum: Carcinoma									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Intestine Small: Jejunum: Granular Cell Tumor Malig									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Intestine Small: Jejunum: Leiomyoma			•••••						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Intestine Small: Jejunum: Leiomyosarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

nal Groups Report Date: 03/20/2010

**Page:** 108

			Male				Female	
#Intestine Small: Site Uns Adenoma	specified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Carcinoma	specified:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Small: Site Uns Carcinoma or Adenoma	specified:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Granular Cell Tumor Ma	specified:							
Overell Includence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Small: Site Uns Leiomyoma	specified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Intestine Small: Site Uns Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 109

Report Date: 03/20/2010

Species: RATS Strain: F 344/N Route: GAVAGE

Vehicle: WATER

			Male			Female			
'Islets, Pancreatic: Adenoma		0/50 (400)	0/50 (00)	0/50 /40/		4/50 (000)	4/50 (00()		
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	2/50 (4%) SD 2.31%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	
Islets, Pancreatic: Carcinoma									
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	0/50 (0%) Mean 2%	2/50 (4%) SD 2%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Islets, Pancreatic: Carcinoma or Adenoma									
Overall Incidence	Total	3/50 (6%) 7/150 (4.67%)	0/50 (0%) Mean 4.67%	4/50 (8%) SD 4.16%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	
Kidney: Pelvis and Transition									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Kidney: Pelvis and Transition Carcinoma or Adenoma		um:							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Kidney: Pelvis and Transition		um:							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 110

			Male				Female	
Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma		4/50 (00/)	0/50 /40/	0/50 (0%)		0/50 (00/)	0/50 (00)	0/50 /00/)
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	2/50 (4%) Mean 2%	0/50 (0%) SD 2%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Benig	jn							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 111

			Male				Female	
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	gnant							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Kidney: Renal Tubule: Nephroblastoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Kidney: Renal Tubule: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Cholangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: WATER

Page: 112

Report Date: 03/20/2010

			Male				Female	
*Liver: Hepatocellular Carcinoma Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hepatocellular Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hepatocellular Carcinoma			1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
*Liver: Hepatocellular Carcinoma,				0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
*Liver: Ito Cell Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Lung: Alveolar/Bronchiolar Aden								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 113

			Male				Female					
*Lung: Alveolar/Bronchiolar Carcinoma  1/50 (2%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%)												
		` '	` '	` ,		` ,	` ,	` '				
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
-ung: -ung: -Alveolar/Bronchiolar Ca	arcinoma or Alv	/eolar/Bronchiolar Adeno	ma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)				
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%				
Lung: Fibrosarcoma		0/50 /00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00()	0/50 (00/)				
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
	10lai	0/150 (0%)		3D 0%	10tai	0/130 (0%)						
ung: Hemangiosarcoma												
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
Lung: Squamous Cell Carcino	ma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
Lymph Node: Hemangiosarcoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 03/20/2010

Page: 114

F	emale		
0/50	(0%)	(0%)	

			Male				Female	
#Mammary Gland: Adenolipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	2/50 (4%) SD 2.31%
#Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
#Mammary Gland: Carcinoma or Adenoma		4/50 (631)	0/50 (051)	0/50 (00)		0/50 /450	0(50 (40))	0/50 (40)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 6/150 (4%)	2/50 (4%) Mean 4%	2/50 (4%) SD 0%
#Mammary Gland: Fibroadenoma								
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	1/50 (2%) SD 1.15%	Total	33/50 (66%) 94/150 (62.67%)	32/50 (64%) Mean 62.67%	29/50 (58%) SD 4.16%
#Mammary Gland: Fibroma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 115

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma or	r Adenoma							
		4/50 (8%)	2/50 (4%)	1/50 (2%)		33/50 (66%)	33/50 (66%)	30/50 (60%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%	Total	96/150 (64%)	Mean 64%	SD 3.46%
Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, o	r Adenoma						
		4/50 (8%)	2/50 (4%)	1/50 (2%)		35/50 (70%)	33/50 (66%)	30/50 (60%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%	Total	98/150 (65.33%)	Mean 65.33%	SD 5.03%
Mesentery: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mesentery: Hemangiosarcoma						0/50 (00/)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mesentery: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 116

			Male				Female		
Nose: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
'Nose: Chondroma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Nose: Squamous Cell Carcin	oma	0/50 (0%)	0/50 (0%)	0/50 (09/)		0/50 /00/\	0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Oral Cavity (Oral Mucos Papilloma Squamous o	sa, Tongue, Phar	ynx, Tooth, Gingiva):							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Oral Cavity (Oral Mucos	sa, Tongue, Phar	ynx, Tooth, Gingiva):							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 117

			Male				Female	
#Oral Mucosa: Squamous Cell Carcinom	na	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Oral Mucosa: Squamous Cell Papilloma	a			0/50 (00)			0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Cystadenoma								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Ovary: Granulosa Cell Tumor Be	enign					0/50 (00/)	0/50 (00/)	0/40 (00/)
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Ovary: Granulosa Cell Tumor Ma	alignant				•••••			
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Granulosa Cell Tumor: B	enign, Maligna	nt, NOS				0/50 (00:)		2/12 (22)
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 118 Report Date: 03/20/2010

Species: RATS Strain: F 344/N Route: GAVAGE Vehicle: WATER

			Male				Female			
*Ovary: Granulosa-Theca Tumor E	Benign					0/50 (00)	0/50 (00/)	0/40 (00/)		
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
*Ovary: Granulosa-Theca Tumor I	<b>Walignant</b>									
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
*Ovary: Tubulostromal Adenoma										
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
*Pancreas: Adenoma								2/22 (201)		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Pancreas: Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Pancreas: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 119

Report Date: 03/20/2010

Route: GAVAGE Vehicle: WATER

			Male			Female				
Pancreas: Mixed Tumor Benign										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Pancreas: Mixed Tumor Malignant										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
*Parathyroid Gland: Adenoma										
		0/48 (0%)	0/50 (0%)	0/49 (0%)		0/46 (0%)	0/48 (0%)	0/48 (0%)		
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/142 (0%)	Mean 0%	SD 0%		
Pituitary Gland: Pars Dista Adenoma										
		11/50 (22%)	20/50 (40%)	15/50 (30%)		22/50 (44%)	16/50 (32%)	24/50 (48%)		
Overall Incidence	Total	46/150 (30.67%)	Mean 30.67%	SD 9.02%	Total	62/150 (41.33%)	Mean 41.33%	SD 8.33%		
Pituitary Gland: Pars Dista Carcinoma	alis or Unspec	cified Site:								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%		
*Pituitary Gland: Pars Dista Carcinoma or Adenoma		cified Site:								
		11/50 (22%)	20/50 (40%)	15/50 (30%)		24/50 (48%)	16/50 (32%)	25/50 (50%)		
Overall Incidence	Total	46/150 (30.67%)	Mean 30.67%	SD 9.02%	Total	65/150 (43.33%)	Mean 43.33%	SD 9.87%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 120

		Male				Female	
alis or Unspec	ified Site:						
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)			Total	0/150 (0%)	Mean 0%	SD 0%
rmedia:							
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
rmedia:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
/osa:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
l otal	0/150 (0%)	Mean 0%	SD 0%	l otal	0/150 (0%)	Mean 0%	SD 0%
	0/50 (0%)	1/50 (2%)	0/50 (0%)				
Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
	0/50 (0%)	1/50 (2%)	0/50 (0%)				
Total	1/150 (0.67%)	Mean 0.67%	` ,				
	Total rmedia:  Total rmedia:  Total	Total 0/150 (0%)  rmedia:  0/50 (0%)  Total 0/150 (0%)  rmedia:  0/50 (0%)  Total 0/150 (0%)  //osa:  0/50 (0%)  Total 0/150 (0%)  Total 1/150 (0.67%)	Alis or Unspecified Site:    0/50 (0%)	Alis or Unspecified Site:    0/50 (0%)	Alis or Unspecified Site:	Alis or Unspecified Site:    0/50 (0%)	Alis or Unspecified Site:    0/50 (0%)   0

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

VAGE

Page: 121

			Male				Female		
Salivary Glands: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Salivary Glands: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Salivary Glands: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Salivary Glands: Schwannoma Malignant		0/50 (00/)	0/50 (00/)	0/50 /00/		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Seminal Vesicle: Adenoma									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	)				
Skeletal Muscle: Fibrous Histiocytoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 122

			Male			Female					
#Skeletal Muscle: Hemangiosarcoma											
Overell besidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: Rhabdomyosarcoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Adenoma		4/50 (004)	4/50 (00)	4/50 (001)		4/50 (00/)	4/50 (001)	0/50 (00/)			
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%			
:::::::::::::::::::::::::::::::::::::		Tumor Benign				4/50 (00)	4/50 (00)	0/50 (001)			
Overell Incidence	Total	1/50 (2%)	1/50 (2%)	1/50 (2%)	Total	1/50 (2%)	1/50 (2%)	0/50 (0%) SD 1.15%			
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	30 ו.וכ%			
#Skin: Basal Cell Adenoma, Bas		umor Benign, or Trichoeլ	oithelioma								
		1/50 (2%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 123

			Male		Female				
Skin: Basal Cell Carcinoma		0.000	0.000 (0.51)	0.000			(00)	0.000 (000)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Skin: Basal Cell Carcinoma c	or Basosguamo	us Tumor (malignant or N	 (OS)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		noma, Basosquamous Tui	mor (benign, malignal	nt or		2/50 (4%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%	
		C, 100 (=,0)							
#Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	noma, Carcinon	na, Basosq. Tumor (M or leratoacanthoma, Trichoep 10/50 (20%) 16/150 (10.67%)	3), Basal Cell Adenon oithelioma 2/50 (4%) Mean 10.67%	na, 4/50 (8%) SD 8.33%	Total	4/50 (8%) 7/150 (4.67%)	3/50 (6%) Mean 4.67%	0/50 (0%) SD 4.16%	
#Skin: Basal or Sq. Cell Carcin	noma, Carcinon Sq Papilloma, Ko	na, Basosq. Tumor (M or leratoacanthoma, Trichoe 10/50 (20%) 16/150 (10.67%)	oithelioma 2/50 (4%) Mean 10.67%	4/50 (8%) SD 8.33%	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%	
#Skin: Basal or Sq. Cell Carcir Adenoma, Papilloma, S Overall Incidence #Skin:	noma, Carcinon Sq Papilloma, Ko	na, Basosq. Tumor (M or l eratoacanthoma, Trichoep 10/50 (20%)	oithelioma 2/50 (4%)	4/50 (8%)	Total Total	` '	` '	` '	
#Skin: Basal or Sq. Cell Carcir Adenoma, Papilloma, S Overall Incidence  #Skin: Fibroma Overall Incidence	noma, Carcinon 6q Papilloma, Ke Total Total	na, Basosq. Tumor (M or leratoacanthoma, Trichoe 10/50 (20%) 16/150 (10.67%)	2/50 (4%) Mean 10.67%  2/50 (4%) 2/50 (4%) Mean 8.67%	4/50 (8%) SD 8.33% 5/50 (10%)		7/150 (4.67%)	Mean 4.67%  0/50 (0%)	SD 4.16% 1/50 (2%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

d Control Animal Groups

VAGE
VATER

Female

Page: 124

			Male				Female	
#Skin: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
				וו עכ וווט%	10tai	0/150 (0%)		טעט עס
#Skin: Fibrosarcoma. Sarcoma.	Mvxosarcom	a, or Fibrous Histiocytom	a					
, , , , , , , , , , , , , , , , , , , ,	,	1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Fibrous Histiocytoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		8/50 (16%)	0/50 (0%)	2/50 (4%)		2/50 (4%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	10/150 (6.67%)	Mean 6.67%	SD 8.33%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

			Male		Female						
#Skin: Lipoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Liposarcoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Neural Crest Tumor		0/50 /(00/)	0/50 /00/	0/50 (00%)		0/50 (000)	0/50 (00/)	0/50 /00/			
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%			
Overali incidence	ıoıaı	0/150 (0%)		3D 0%	Total	0/150 (0%)	Mean 0%	ט עס			
#Skin: Neural Crest Tumor, Mal	ignant										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Neurofibroma or Schwar	nnoma benign										
	_	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Neurofibrosarcoma or Sc	chwannoma (m	nalignant or NOS)									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 126

			Male				Female			
#Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)										
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
#Skin: Sarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Skin: Schwannoma Benign		•••••								
· ·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Skin: Schwannoma Malignant		•••••								
•		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
#Skin: Squamous Cell Carcinor	na									
·		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Carcinon or Carcinoma	na, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant	or NOS),						
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Report Date: 03/20/2010

Page: 127

Species: RATS Strain: F 344/N

Vehicle: WATER

			Male			Female			
#Skin: Squamous Cell Papillom	a								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
					10tai	1/130 (0.07 /6)			
#Skin: Squamous Cell Papillom	a or Panilloma								
oquamous och i apmom	a or r apmome	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Skin: Squamous Cell Papillom	a, Papilloma, S	Squamous Cell Carcinom 9/50 (18%)	a or Keratoacanthom 1/50 (2%)	<b>a</b> 3/50 (6%)		2/50 (4%)	3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	13/150 (8.67%)	Mean 8.67%	SD 8.33%	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%	
#Skin: Squamous Cell Papillom	a, Papilloma, o								
Overall Incidence	Total	9/50 (18%) 11/150 (7.33%)	0/50 (0%) Mean 7.33%	2/50 (4%) SD 9.45%	Total	2/50 (4%) 5/150 (3.33%)	3/50 (6%) Mean 3.33%	0/50 (0%) SD 3.06%	
#Skin: Trichoepithelioma					•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Skin: Sebaceous Gland: Adenoma									
		0/50 (00/)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 128

			Male				Female			
#Skin: Sebaceous Gland: Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)	`	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%	
Spinal Cord: Astrocytoma Benign										
		0/50 (0%)	0/50 (0%)	0/50 (	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%	
Spinal Cord: Astrocytoma Malignant										
		0/50 (0%)	0/50 (0%)	`	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%	
Spinal Cord: Glioma Malignant										
	<b>-</b>	0/50 (0%)	0/50 (0%)	,	(0%)	<b>.</b>	0/50 (0%)	1/50 (2%)	0/50 (0%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Spleen: Fibrosarcoma										
		0/50 (0%)	0/50 (0%)	,	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%	
Spleen: Fibrous Histiocytoma										
		0/50 (0%)	0/50 (0%)	`	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 129

			Male		Female			
Spleen: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Forestomach: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	•			•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 130

			Male		Female			
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma								
O II I I I	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (001)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
overali incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	
Stomach, Glandular: Lipoma								
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Testes: Adenoma		44/50 (000/)	45/50 (000)	40/50 (000%)				
Overall Incidence	Total	44/50 (88%)	45/50 (90%) Mean 91.33%	48/50 (96%) SD 4.16%				
overali incidence	Total	137/150 (91.33%)	wean 91.33%	SD 4.10%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: WATER

Route: GAVAGE

Length of Study: CHRONIC

trol Animal Groups Report Date: 03/20/2010

Page: 131

			Male			Female			
*Testes: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%					
*Thymus: Thymoma Benign									
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/48 (0%) 1/144 (0.69%)	0/48 (0%) Mean 0.69%	1/48 (2%) SD 1.2%	
*Thymus: Thymoma Malignant								(200)	
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/48 (0%) 1/144 (0.69%)	1/48 (2%) Mean 0.69%	0/48 (0%) SD 1.2%	
*Thymus: Thymoma NOS		0/40 (00/)	0/50 (09/)	0/49 (09/)		0/49 /00/\	0/49 (09/)	0/49 (00/)	
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/48 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%	
*Thymus: Thymoma: Benign, Maligi									
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/48 (0%) 2/144 (1.39%)	1/48 (2%) Mean 1.39%	1/48 (2%) SD 1.2%	
*Thyroid Gland: C-Cell: Adenoma									
Overall Incidence	Total	6/50 (12%) 18/150 (12%)	11/50 (22%) Mean 12%	1/50 (2%) SD 10%	Total	5/50 (10%) 22/150 (14.67%)	6/50 (12%) Mean 14.67%	11/50 (22%) SD 6.43%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Page: 132

Report Date: 03/20/2010

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		6/50 (12%)	11/50 (22%)	1/50 (2%)		5/50 (10%)	6/50 (12%)	12/50 (24%)
Overall Incidence	Total	18/150 (12%)	Mean 12%	SD 10%	Total	23/150 (15.33%)	Mean 15.33%	SD 7.57%
*Thyroid Gland: Follicular Cell Adenoma	:							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Thyroid Gland: Follicular Cell Carcinoma	:							
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Tissue NOS: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 133

			Male				Female	
#Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma c Overall Incidence	or Papilloma	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overali incidence	ı otal 	0/150 (0%)	wean u%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Papilloma		0/50 (00()	0/50 (00()	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
tTooth: Adamantinoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (001)	0/50 (00)	0(50 (00))		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overell Insidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

GAVAGE WATER Page: 134

			Male		Female			
Urinary Bladder: Carcinoma or Papilloma								
S	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma		0/50 (00/)	0/50 (00()	0/50 (00()		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	ı olal	0/130 (0/6)					Weall 070	
Urinary Bladder: Papilloma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Adenoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
Uterus: Carcinoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Red Control Animal Groups

**Page:** 135

Report Date: 03/20/2010

Route: GAVAGE Vehicle: WATER

	Male	Female	
#Uterus: Deciduoma Benign		0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	` ,	SD 0%
#Uterus: Hemangioma			
Overall Incidence	Total	(111)	0/50 (0%) SD 0%
#Uterus: Hemangiosarcoma			
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyosarcoma		0/50 (0%) 0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Polyp Stromal			
Overall Incidence	Total	,	8/50 (16%) SD 1.15%
#Uterus: Sarcoma			
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 136 Report Date: 03/20/2010

Species: RATS Strain: F 344/N Route: GAVAGE Vehicle: WATER

			Male				Female	
#Uterus: Sarcoma Stromal								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal or Poly	n Stromal							
Overall Incidence	p ou ou u				Total	7/50 (14%) 23/150 (15.33%)	8/50 (16%) Mean 15.33%	8/50 (16%) SD 1.15%
#Uterus: Schwannoma Malignant	•••••							
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
#Vagina: Polyp								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Adenoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 137

			Male		Female			
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied